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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Catherine A. Pipenhagen

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/726,966	Applicant(s) PIPENHAGEN ET AL.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-33, 37-40, 42, 43 and 45-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 7-30, 43 and 47-54 is/are allowed.
- 6) ☒ Claim(s) 31, 33, 37-40, 42, 45 and 46 is/are rejected.
- 7) ☒ Claim(s) 32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 31, 33, 45, and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (5,531,759). Kensey et al. disclose, at least in figures 1-6 , 9, and 13; a tissue puncture sealing device (with respect to claims 31 and 33) including an insertion sheath (34) having first and second ends, a carrier tube (32), an anchor (38) disposed inside the insertion sheath at the first end thereof and outside of the carrier tube at the first end thereof (at a stage of deployment of the anchor between figures 1 and 2), a sealing plug (36) disposed inside the carrier tube at the first end thereof, where a portion of the anchor is positioned radially adjacent to (i.e., near to) an outer diameter of the carrier tube, where the sealing plug is folded at least once (see fig. 6), where the tissue puncture device is in an undeployed configuration where the tissue puncture device is not inserted into a patient (e.g., at assembly of the device or at demonstration of the device outside of a patient); and where the sealing plug is folded from an original V-shape (see fig. 6) to a rectangular shape (see fig. 1). With respect to claims 45 and 46, Kensey et al. also disclose a filament (42) and a sealing plug that is generally V-shaped (in cross-section, as seen in fig. 9) when the sealing plug is open, laid out flat, and unfolded (relative to the folded configuration as seen in fig. 6), where

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the sealing plug comprises a plurality of holes (48, 50), where the tissue puncture closure device is in an undeployed configuration (see fig. 6), where the tissue puncture closure device is configured so that applying a tension force to the filament compresses and holds the sealing plug and the anchor together (e.g., see fig. 6).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 31, 37-40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt et al. (6,508,828). Akerfeldt et al. disclose the invention substantially as claimed. Akerfeldt et al. disclose, in figures 1, 4, and 6-18, a tissue puncture closure device and a method of sealing an internal tissue puncture having a carrier tube (24 or 22), an insertion sheath (24), and a closure device including an anchor (2) and a sealing plug (18) that is folded at least once or from a V-shape (fig. 18) into a substantially straight shape, and a filament (12), where applying a tension force to

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the filament compresses and holds the sealing plug and the anchor together (e.g., see figures 1 and 4), where a portion of the anchor is positioned radially adjacent to (i.e., radially inward and near to) an outer diameter of the carrier tube, the portion of the anchor being flush with the outer diameter of the carrier tube (as the anchor moves partially out of the carrier tube, but before deployment to a surgical site), where the sealing plug includes a plurality of holes (at each end of the plug, where a filament may enter) and where the sealing plug has a V-shape when it is unfolded (see the V-shape at each pointed end of the sealing plug as seen in fig. 5). However, Adkerfeldt et al. do not disclose that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug, when the closure device is in an undeployed configuration before insertion into the internal tissue puncture (see fig. 8). Nevertheless, Akerfeldt et al. disclose, in figures 15 and 17, that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug when parts 41 and 42 are moved along filament (12). Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to move parts 41 and 42 within the carrier tube (as shown in figures 8, 10, and 11), so that the sealing plug is folded so that one portion of the sealing plug is in contact with another portion of the sealing plug (while the closure device is in an undeployed configuration within the carrier tube). Such a narrowed configuration of the sealing plug would ease its deployment through a puncture in a vessel.

Akerfeldt et al. also do not disclose that the anchor is positioned outside of the carrier tube. Nevertheless, it would have been obvious to one having ordinary skill in

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the art at the time the invention was made to position the anchor outside of the carrier tube before its insertion within the carrier tube in a known technique of assembling the device prior to its deployment.

Allowable Subject Matter

5. Claims 1-5, 7-30, 43, and 47-54 are allowed.
6. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination discloses a tissue puncture closure device having, inter alia, a carrier tube, a filament, an anchor, and a sealing plug or first external component, and a second external component folded and engaged with the first external component, where the external component comprises a sponge material, where the sealing plug comprises an X-shape in cross-section and the filament alternately extends through holes in two cross members of the sealing plug in a spiral pattern or at least four holes in the sealing plug, where the external component comprises two legs folded along a centerline, and where first and second external components are each folded into generally U-shapes and the filament passes through one hole in the first component and one hole in the second component before passing through a hole in the anchor, and where the filament passes through another hole in the first component and another hole in the second component after passing through the hole in the anchor. Also, none of the prior art of record, alone or in combination discloses a tissue puncture closure device having, inter alia, an insertion sheath, a filament, an anchor, and a sealing plug or first external component, and a second external component folded and engaged with the first external component, where the

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sealing plug is tri-folded into a shape with an S-shaped cross-section, where folds are substantially parallel to a longitudinal axis of the sealing plug

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Claim 32 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination discloses a tissue puncture closure device having, inter alia, an insertion sheath, a filament, an anchor, and a sealing plug or first external component, and a second external component folded and engaged with the first external component, where the sealing plug is tri-folded into a shape with an S-shaped cross-section, where folds are substantially parallel to a longitudinal axis of the sealing plug.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

9. The rejection under 35 U.S.C. 112, 2nd paragraph, is hereby withdrawn.

Applicant's arguments with respect to claims 45 and 46 have been considered but are

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moot in view of the new ground(s) of rejection. Arguments with respect to claims 31, 33, 37-40, and 42 have been considered but are not persuasive. That is, Kensey et al. and Akerfeldt et al. indeed disclose an anchoring member or sealing member, where a portion of the anchoring member or sealing member is positioned radially adjacent to (i.e., radially inward and near to) an outer diameter of the carrier tube. Even the Applicant has admitted that the anchoring member for Kensey is "disposed at a location radially inward relative to an inner diameter surface of the deployment instrument," while for Akerfeldt et al, the sealing member is "spaced radially inward relative to an inner diameter surface of the introducer." In turn, the anchoring member or sealing member is positioned radially relative to an outer diameter of the carrier tube. Additionally, the ENCARTA World English Dictionary defines "adjacent" to include "neighboring: situated near or close to something or each other, especially without touching." And given the broadest reasonable interpretation of "adjacent," the anchoring member or sealing member is not only radially positioned relative to an outer diameter of the carrier tube, the anchoring member or sealing member is adjacent to (i.e., near to) the outer diameter of the carrier tube.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/

Primary Examiner, Art Unit 3773